Translation

PATENT COOPERATION TREATY

PCT

520981

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference OB/BR42844WO	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/FR2003/002252	International filing date (*day/month/year*) 16 juillet 2003 (16.07.2003)	Priority date (*day/month/year*) 19 juillet 2002 (19.07.2002)
International Patent Classification (IPC) or national classification and IPC A61M 5/50, 5/24, 5/32		
Applicant BECTON DICKINSON FRANCE		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
26 janvier 2004 (26.01.2004)	15 September 2004 (15.09.2004)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/FR2003/002252

I. Basis of the report

1. This report has been drawn on the basis of (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

☐ the international application as originally filed.

☒ the description, pages 1-7, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____,
pages _____, filed with the letter of _____.

☒ the claims, Nos. 1-8, as originally filed,
Nos. _____, as amended under Article 19,
Nos. _____, filed with the demand,
Nos. _____, filed with the letter of _____,
Nos. _____, filed with the letter of _____.

☒ the drawings, sheets/fig 1/7-7/7, as originally filed,
sheets/fig _____, filed with the demand,
sheets/fig _____, filed with the letter of _____,
sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-8	YES
	Claims		NO
Inventive step (IS)	Claims	1-8	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-8	YES
	Claims		NO

2. Citations and explanations

1. D1 (WO 01/45776 A), which is considered to be the prior art closest to the subject matter of claim 1, describes (the references between parentheses apply to said document) (cf. page 8, line 17 to page 9, line 5) an injection device with the following features:

A device (10) for injecting a product, clearly intended for medical use, including

- a body (20) receiving a hollow injection needle (60) and a receptacle (37) containing the product to be injected; the needle (60) is connected to the body (20) while being movable relative thereto between an injection position and a retracted position;
- a thumb rest (35) slidably mounted on the body (20) and movable relative thereto for performing the injection; the receptacle (37) is closed at one end;
- means (22, 34, 42) for supporting the needle (60), which normally hold the needle (60) in the injection position but can be released to free the movement of the needle (60) towards the retracted position;
- a plunger (30) engaged in the receptacle (37), arranged so that, in a first arrangement of the plunger (30) or relative position of said plunger (30) and said receptacle (37), the receptacle (37) is closed, thereby isolating the product relative to the outside of the

receptacle (37) and,

- respective means (42), *on the distal side of the thumb rest (35)*, for actuating the means (42) for supporting the needle (60) and the means for supporting the receptacle (37), whereby, on completion of the injection, the means (42) for supporting the needle (60) can be released before the means for supporting the receptacle (37) are released, or simultaneously with the release thereof.

The subject matter of claim 1 differs from this known injection device in that:

- the receptacle (10) is connected to the thumb rest (9) while being movable relative thereto between an injection position and a retracted position;
- the means (45, 39, 41) for supporting the receptacle (10) normally hold the receptacle (10) in a position enabling the injection to be performed and can be released to free the movement of the receptacle (10) to the retracted position;
- in a second arrangement of the plunger (11) or relative position of said plunger (11) and the receptacle (10), the plunger (11) is arranged to enable the product to pass towards the outside of the receptacle (10).

The subject matter of claim 1 is therefore novel (PCT Article 33(2)).

The technical problem that the present invention is intended to solve can therefore be considered to be that of improving reliability of the injection and safety with respect to the risk of accidental needle sticks from an injection device.

The solution, as proposed in claim 1 of the present

application, consists in releasing the means (45, 39, 41) for supporting the receptacle (10) and the injection needle (4) on completion of the injection, thereby freeing said two components (10, 4) from their respective supports so that they can be retracted safely and effectively inside the thumb rest (9).

This solution is not obvious from the device as disclosed in D1 (see page 8, line 17 to page 9, line 5), since the plunger (32) must achieve two contradictory goals, namely ensuring:

(a) sealing of the receptacle (37), which necessarily involves a degree of friction between the plunger (32) and the inner wall of the receptacle (37);

(b) and free sliding of the plunger on the same surface when moving towards its retracted position.

Consequently, the subject matter of claim 1 meets the requirements of PCT Article 33(3).

Claims 2 to 8 are dependent on claim 1 and thus also comply, as such, with the PCT requirements of novelty and inventive step.

2. As stated below, certain features of the injection device mentioned in claim 1 serve rather to explain the method for using the device than to define the device clearly in terms of technical features. The limitations that these features are intended to define are not clear from said claim, contrary to the requirement of PCT Article 6.

2.1 The features relating to the method of use are as follows:

lines 27 to 29 "enabling, on completion of the injection,

the means for supporting the needle 4 to be released prior to the release of the means for supporting the receptacle 10, or simultaneously therewith".

2.2 To understand the way in which the injection device functions, the way in which the plunger 11 can be moved within the receptacle 10 should be clearly defined.

2.3 Apparently, the means for connecting the receptacle 10 to the thumb rest 9 (see page 8, line 11) are the same as those (45, 39, 41) for supporting the receptacle (see line 17). This is not clear from the definition of the present claim.